

DOCKETS MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5630 FISHERS LANE ROOM 1061  
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

9 8 4 7 '99 JUL 29 A9 :02

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Comments:

*The MOU, as written, would prohibit my receiving my physician ordered medication. There should be no restrictions unless applied to non-compounded prescriptions also.*

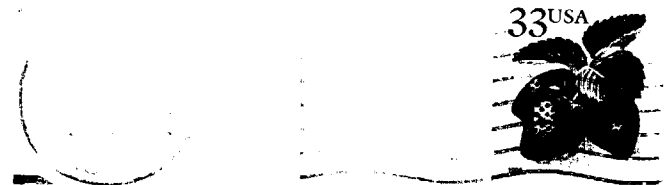
Signed: Mary A. Donato

State of Residence: Ohio

98N-1265

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